EU DECLARATION OF CONFORMITY

Manufacturer

Name:	**Rehadapt Engineering GmbH & Co. KG**
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This declaration of conformity is issued under the sole responsibility of the manufacturer:

Object of the declaration

Product group:	**Rehadapt keyguards**
Description:	Rehadapt keyguards are accessories that are secured on the touchscreen display of a tablet. They feature cutouts to support the user and prevent them from pressing buttons by accident.
Basic UDI-DI:	**++B896KeyguardsVW**
Article numbers:	The products encompassed in this product family are listed in the table on page 2.
Classification:	**Class 1 medical devices**

The object of the declaration described above is in conformity with the relevant Union harmonization legislation:

- Medical Device Regulation 2017/745

References to the relevant harmonized standards used, or references to the specifications in relation to which conformity is declared:

- **EN ISO 13485:2016:** Medical devices – Quality management systems – Requirements for regulatory purposes
- **EN ISO 14971:2019** Application of risk management to medical devices

Additional information

N/A

Signed for and on behalf of:

Ulrich K Ehlert
CEO

List of medical devices belonging to the product group "Rehadapt keyguards"

Art. Nr.	Name	UDI-DI
18.2000	FF-GoTalkNow-10.2 2x2	*+B89618200000*
18.2001	FF-GoTalkNow-10.2 2x2 MB	*+B89618200101*
18.2002	FF-GoTalkNow-10.2 3x3	*+B89618200202*
18.2003	FF-GoTalkNow-10.2 3x3 MB	*+B89618200303*
18.2004	FF-GoTalkNow-10.2 4x4	*+B89618200404*
18.2005	FF-GoTalkNow-10.2 4x4 MB	*+B89618200505*
18.2006	FF-GoTalkNow-10.2 5x5 MB	*+B89618200606*
18.2007	FF-GoTalkNow-10.2 6x6 MB	*+B89618200707*
18.2100	FF-MetaTalk-10.2 3x5 MB	*+B89618210001*
18.2101	FF-MetaTalk-10.2 4x7 MB	*+B89618210102*
18.2102	FF-MetaTalk-10.2 5x9 MB	*+B89618210203*
18.2103	FF-MetaTalk-10.2 6x11 MB	*+B89618210304*
18.2200	FF-Predictable-10.2 QWERTZ MB	*+B89618220002*
18.2201	FF-Predictable-10,2 QWERTZ	*+B89618220103*
18.2202	FF-Predictable-10,2 QWERTZ R	*+B89618220204*
18.2300	FF-SnapCoreFirst-10.2 3x3 MB TB	*+B89618230003*
18.2301	FF-SnapCoreFirst-10.2 3x4 MB TB	*+B89618230104*
18.2302	FF-SnapCoreFirst-10.2 4x4 MB TB	*+B89618230205*
18.2303	FF-SnapCoreFirst-10.2 5x5 MB TB	*+B89618230306*
18.2304	FF-SnapCoreFirst-10.2 6x6 MB TB	*+B89618230407*
18.2305	FF-SnapCoreFirst-10.2 7x7 MB TB	*+B89618230508*
18.2306	FF-SnapCoreFirst-10.2 7x9 MB TB	*+B89618230609*
18.2307	FF-SnapCoreFirst-10.2 8x10 MB TB	*+B8961823070A*

19.5.2021